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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MICHAEL PARDI, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

vs.

TRICIDA, INC., and GERRIT KLAERNER,

Defendants.

Case No. 5:21-cv-00076-LHK

CLASS ACTION

DEFENDANTS TRICIDA, INC. AND GERRIT KLAERNER'S MOTION TO DISMISS THE AMENDED COMPLAINT

Assigned to: Hon. Lucy H. Koh

Date: December 9, 2021
Time: 1:30 p.m.
Courtroom 8, 4th Floor

NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

Please take notice that on December 9, 2021, at 1:30 p.m., defendants Tricida, Inc. and its President and Chief Executive Officer Gerrit Klaerner (collectively Tricida, or Defendants) will bring for hearing this motion to dismiss, before the Honorable Judge Lucy H. Koh, San Jose Courthouse, Courtroom 8, 4th Floor, 280 South 1st Street, San Jose, CA 95113.

As set forth in the attached memorandum, the Court should dismiss this action in its entirety under Rule 12(b)(6) because Lead Plaintiff Jeffrey M. Fiore (Plaintiff) has failed to state a claim on which relief may plausibly be granted.

Plaintiff asserts a claim against Defendants under Section 10(b) of the Securities Exchange Act (Exchange Act), 15 U.S.C. § 78j(b). Plaintiff fails, however, to plead that claim with the particularity required by the Private Securities Litigation Reform Act. Specifically, Plaintiff has (1) failed to plead with particularity that Defendants made any materially false or misleading statement; and (2) failed to establish a strong inference of intentional fraud.

Plaintiff also asserts a control person claim against Klaerner under Section 20(a) of the Exchange Act, 15 U.S.C. § 78t. This claim fails because Plaintiff has not established a primary violation under Section 10(b).

This motion is based on the attached memorandum, the Request for Judicial Notice, the Declaration of Sarah Hemmendinger and all attached exhibits, and such argument as may be presented before or after the hearing on this matter.

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I. INTRODUCTION

Tricida is a clinical-stage biopharmaceutical company developing the drug veverimer as a treatment for metabolic acidosis, a condition that is both a complication and a cause of chronic kidney disease (CKD). Gerrit Klaerner is Tricida's founder, President and CEO. After completing a successful pivotal Phase 3 trial for veverimer, Tricida held its initial public offering in June 2018. Over the next two years, Tricida consistently updated investors on its business and regulatory strategy, as well as on the risk that the FDA might fail to approve veverimer through the regulatory pathway Tricida was pursuing—the FDA's Accelerated Approval Program. Tricida submitted its New Drug Application (NDA) for veverimer in August 2019, and the FDA accepted that submission in October 2019.

On July 14, 2020, the FDA unexpectedly informed Tricida that deficiencies in the NDA precluded completion of the steps remaining in the approval process. On August 21, 2020, the FDA specified in a Complete Response Letter that it required additional data, beyond that supplied by the Phase 3 trials, on the magnitude and durability of veverimer's treatment effect and on the application of that effect to the U.S. population. The FDA also gave Tricida options for addressing those issues, and Tricida continues to this day to conduct the confirmatory trial it initiated in late 2018.

According to Plaintiff, who claims to have lost $2219 by investing in Tricida stock, this course of events amounts to deliberate fraud, and Defendants are accordingly liable under Section 10(b) of the Exchange Act. But Plaintiff has not come close to demonstrating, with the heightened particularity required by the Private Securities Litigation Reform Act (PSLRA), that Defendants made false or misleading statements, let alone acted with a deliberate intent to defraud investors.

False or misleading statements. The great majority of the statements Plaintiff challenges relate to the location of Tricida's Phase 3 trial sites. The heart of Plaintiff's case is that Tricida concealed the fact that the sites were located in Eastern Europe and thereby also concealed the risk that the FDA would conclude that the Phase 3 trial results were inapplicable to U.S. patients. This contention borders on the frivolous. Tricida did not conceal but repeatedly disclosed, in medical journals and on government websites, the location of each of the Phase 3 trial sites.

Plaintiff next contends that during a June 2019 investor presentation, Klaerner

misrepresented the nature of the FDA's Accelerated Approval Program, telling investors that it was "simpler and easier" than other regulatory pathways. This is fiction. "Simpler and easier" are Plaintiff's words, not Klaerner's. In the very statements Plaintiff challenges, Klaerner advised investors, as Tricida had done since its IPO, that the Accelerated Approval Program requires drug sponsors not only to demonstrate efficacy through a Phase 3 surrogate endpoint trial for initial approval, but also to prove a clinical benefit through a longer-term post-approval confirmatory trial.

Plaintiff also challenges certain statements Tricida made about the design of that confirmatory trial, called VALOR-CKD. Tricida consistently told investors that it anticipated that 1600 patients would be randomized in the trial. Plaintiff now contends that Tricida should have enrolled more patients to sufficiently power the study. Under settled law, this is a non-justiciable attack on trial design; it does not show that any challenged statement was false or misleading.

Plaintiff finally challenges statements Tricida made about its interactions with FDA staff on May 1, 2020, claiming that Tricida misrepresented what the FDA told the Company on that date about the reasons for a canceled Advisory Committee meeting. That allegation is entirely devoid of support: Plaintiff cites no source for its contentions about what the FDA said on May 1, 2020.

Scienter. Plaintiff's claims are equally defective on scienter grounds. Plaintiff cannot overcome, as he must under controlling law, the obvious benign inference that arises from the facts alleged: that Tricida strove earnestly to put veverimer, its sole drug candidate, on a path for approval. The contrary inference Plaintiff seeks to support—that Tricida persisted for years, and at enormous expense, with a drug candidate and a regulatory strategy it knew was flawed—is not supported by any fact or theory Plaintiff pleads. Plaintiff's two confidential witnesses have nothing to say about Tricida's belief in its clinical trials or chance of approval. Plaintiff's conclusory "core operations" allegations do not comport with this Court's application of that doctrine. And the stock sales Plaintiff claims furnished an improper motivation for Klaerner were non-discretionary, while Tricida's stock offerings were routine corporate transactions. On scienter grounds, on falsity grounds, or on both, the Court should dismiss Plaintiff's complaint in its entirety.

II. BACKGROUND

Veverimer and Tricida's Phase 3 trials. In its June 2018 IPO offering documents, Tricida

described in detail the clinical trials in which it was testing veverimer, as well as the regulatory pathway through which it sought approval of the drug. Veverimer, as noted, is a treatment for metabolic acidosis, which is commonly caused by CKD and leads to the progression of CKD to end-stage renal disease. Ex. 1 at 2.[1] Metabolic acidosis is a chronic and serious disease in which a patient's kidneys can no longer excrete or reabsorb acid, causing excessive acid to build up in the patient's body. *Id.* At the time of the IPO, the FDA had not approved any chronic therapy for treating metabolic acidosis. *Id.* This remains true today. Most patients receive no treatment for the condition at all. *Id.* Unapproved treatments include supplements such as sodium bicarbonate, which neutralize acid and thereby increase blood bicarbonate levels. But these treatments also deliver a large daily dose of sodium, which is undesirable for patients with CKD. *Id.*

Tricida developed veverimer against this background. Veverimer is an oral polymeric drug that works by selectively binding to acids in the GI tract. *Id.* at 2-3. The drug is not systemically absorbed into a patient's body; the patient excretes the acid-bound polymer through feces.

At the time of the IPO, Tricida had already completed successful Phase 1/2 and Phase 3 trials. *Id.* at 3-4. The pivotal Phase 3 trial, TRCA-301, ran from September 2017 through May 2018; it was a double-blind placebo-controlled study conducted at 47 sites in the U.S. and Europe. *Id.* at 107-08. The 217 patients enrolled in TRCA-301 suffered from low blood bicarbonate levels—between 12 and 20 mEq/L. A normal blood bicarbonate level is 22 to 29 mEq/L. *Id.*[2]

The primary endpoint of TRCA-301 was an increase in blood bicarbonate level of 4 mEq/L, or achievement of a blood bicarbonate level of in the normal range of 22 to 29 mEq/L at the end of the 12-week treatment period. *Id.* Patients who met one or both of these conditions were deemed responders. The trial met the primary endpoint: 59.2% of the patients in the treatment group—as opposed to 22.5% of the patients in the placebo group—were responders. *Id.* The trial also met its secondary endpoint, which compared the increase in blood bicarbonate levels between the veverimer and placebo groups. The difference between the two groups was statistically significant. *Id.*

[1] "Ex. _" citations refer to the exhibits to the concurrently-filed Declaration of Sarah Hemmendinger. "¶ _" and "Claims Chart No. _" citations in this brief refer to the Amended Complaint, Dkt. 72.

[2] The unit "mEq/L" stands for milliequivalents per liter. An "equivalent" is the amount of a substance that reacts with one mole of another substance.

In addition to the completed TRCA-301 study, Tricida was conducting a related Phase 3 trial at the time of the IPO—TRCA-301E, an extension of TRCA-301 that tested the safety and durability of effect of veverimer over a longer period. *Id.* at 115. Patients who proceeded from TRCA-301 to TRCA-301E received treatment for an additional 40 weeks, for a total of 52 weeks. Tricida first reported the results of the extension trial in March 2019. TRCA-301E met its primary endpoint as well as all secondary endpoints. The drug was shown to be very safe and well-tolerated: Patients treated with veverimer had *lower* dropout rates, *fewer* serious adverse events and *fewer* gastrointestinal adverse events than patients in the placebo group. Ex. 2 at 13.

The secondary endpoints in TRCA-301E measured, among other things, changes in physical function. Here too, the trial was a success. Patients on veverimer reported statistically significant improvements in quality of life, and performed better on a repeated sit-to-stand test than patients on placebo. *Id.* at 13-14. The results of TRCA-301 and 301E were published in back-to-back issues of *The Lancet* in March 2019 and June 2019. ¶ 68; Ex. 5 at 4.

The FDA's Accelerated Approval Program. Throughout the purported class period (which runs from June 28, 2018 through February 25, 2021), Tricida discussed its successful Phase 3 trials within the context of the regulatory approval pathway it had chosen to pursue—the FDA's Accelerated Approval Program. Both before and after it filed its NDA in August 2019, Tricida provided investors with the following facts about Accelerated Approval (among others):

> The FDA's Accelerated Approval Program allows for drugs for serious conditions that address an unmet medical need to be approved based on a surrogate endpoint that is reasonably likely to predict clinical benefit. Surrogate endpoints are used instead of clinical outcomes in some clinical trials. Surrogate endpoints are used when the clinical outcomes might take a very long time to study, or in cases where the clinical benefit of improving the surrogate endpoint, such as controlling blood pressure, is well understood. Clinical trials are needed to show that surrogate endpoints can be relied upon to predict, or correlate with, clinical benefit. Surrogate endpoints that have undergone this testing are called validated surrogate endpoints and those are accepted by the FDA as evidence of benefit. . . .
>
> Surrogate endpoints that the FDA determines are reasonably likely to predict clinical benefit may be used to support approval, in some cases, but are not yet validated. This is accomplished under the FDA's Accelerated Approval Program, which is intended to provide patients with serious diseases more rapid access to promising therapies. Because such surrogate endpoints have not been validated, sponsors relying on them are generally required to verify the predicted clinical benefit of their products with confirmatory postmarketing clinical trials.

Ex. 1 at 114; Ex. 2 at 16-17. Tricida told investors that it believed veverimer was eligible for

approval under the Accelerated Approval Program because, among other things, "[w]e believe that blood bicarbonate is an appropriate surrogate endpoint and that increasing blood bicarbonate is reasonably likely to predict slowing of progression of CKD." Ex. 1 at 115.

Tricida also described its VALOR-CKD confirmatory trial—which remains ongoing today—in detail throughout the purported class period:

> As a condition of filing our NDA pursuant to the Accelerated Approval Program, we have committed to conduct our confirmatory postmarketing trial, VALOR-CKD, which is designed to demonstrate that [veverimer] provides a clinical benefit (i.e., improves how the patient feels, functions, or survives) in addition to increasing blood bicarbonate levels. . . . The protocol for the VALOR-CKD trial was designed in collaboration with a steering committee of international key opinion leaders in the fields of chronic kidney disease progression and metabolic acidosis and with input from the FDA.
>
> The primary endpoint of the VALOR-CKD trial compares the time to first renal event . . . in [veverimer]-treated subjects versus subjects in the placebo group. . . .

Ex. 2 at 17-18. Renal events are defined using various measures of kidney function. *Id.*

Tricida further provided investors with a detailed overview of the FDA approval process generally, warning that "[n]otwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval," and that "[t]he FDA may disagree with our trial design or interpret data from nonclinical studies and clinical trials differently than we interpret the same data." Tricida provided additional detailed warnings about the risks throughout the purported class period. Highlights include the following:

> We will attempt to secure approval of [veverimer] from the FDA through the use of the Accelerated Approval Program, but such mechanism may not actually lead to a faster development or regulatory review or approval process.
> . . .
>
> We have sought feedback from the FDA on our ability to seek and receive approval for [veverimer] under the Accelerated Approval Program, but there can be no assurance that the FDA will ultimately agree that the results . . . will be sufficient to support such approval.
> . . .
>
> [C]onducting clinical trials in foreign countries presents additional risks . . . . [T]he FDA may determine that clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product when administered in U.S. patients and are thus not supportive of an NDA approval in the United States.
> . . .
>
> Because we are developing a product candidate for the treatment of a disease or condition on the basis of an unvalidated surrogate endpoint there are increased risks that the FDA . . . may find that our clinical program provides insufficient evidence of clinical benefit, may have difficulty analyzing and interpreting the results of our clinical program, and may delay or refuse to approve [veverimer].

Ex. 1 at 17, 18, 22, 40; Ex. 5 at 45, 46, 50, 64.

FDA interactions and communications. Tricida regularly updated the market on its interactions with the FDA. In September 2019, Tricida reported that it had filed its NDA the previous month. On November 14, 2019, Tricida reported that the FDA had accepted its application and had informed the Company that it intended to hold an Advisory Committee meeting to review the NDA. Ex. 3 at 4.

In its first-quarter 2020 earnings call, held on May 7, 2020, Tricida reported on its most recent interaction with the FDA, the May 1, 2020 late-cycle meeting. Tricida told investors that it had addressed two principal review issues: "the magnitude and durability of the treatment effect on the surrogate [marker] serum bicarbonate" and "the clinical benefit that the U.S. patients get." Ex. 15 at 5, 10. Tricida also told investors that the FDA had informed it that due in part to logistical challenges caused by COVID-19, the FDA no longer planned to hold an Advisory Committee meeting for veverimer. ¶ 101. Tricida's May 7, 2020 statements are the last Plaintiff challenges.

On July 15, 2020, Tricida announced bad news. The previous day, the FDA had told Tricida that it had identified "deficiencies" in the NDA—which the FDA did not then specify—and that this precluded discussion of the remaining steps in the approval process. ¶ 36. Tricida's stock price fell.

Tricida again discussed the deficiency notice in its second-quarter Form 10-Q, filed August 6, 2020. Tricida stated that in light of the deficiency notice, it now expected to receive a Complete Response Letter (CRL), which the FDA issues when it has decided not to approve an NDA. ¶ 102.

The FDA issued its CRL on August 21, 2020, and on August 24, 2020, Tricida discussed its contents with investors: "According to the CRL, the FDA is seeking additional data beyond the TRCA-301 and TRCA-301E trials regarding the magnitude and durability of the treatment effect of veverimer on the surrogate marker of serum bicarbonate and the applicability of the treatment effect to the U.S. population." ¶ 112. Tricida also noted that the FDA had "expressed concern" in the CRL "as to whether the demonstrated effect size would be reasonably likely to predict clinical benefit." *Id.* Tricida's stock price fell once more. ¶ 113. Plaintiff alleges that Tricida's stock price fell again on October 29, 2020 (after Tricida reported on its End-of-Review meeting with the FDA), on December 8, 2020 (after Tricida announced that it had revised the protocol for VALOR-CKD), and on February 25, 2021 (after Tricida announced that the FDA had issued an Appeal Denied

Letter, denying an intra-agency appeal the Company had filed in December 2020). ¶¶ 116, 118, 121.

Plaintiff's allegations. Plaintiff Jeffrey Fiore purchased Tricida stock on April 9, 2020 and July 16, 2020. Dkt. 12-3. The latter purchase post-dates both Tricida's announcement that it had received a deficiency notice and the stock drop that followed. Plaintiff claims to have lost $2219 on his investments. *Id.* In the Amended Complaint, filed June 1, 2021, Plaintiff does not challenge any statements in which Tricida reported clinical trial results. Nor does Plaintiff challenge any statements—save two on June 12, 2019—in which Tricida described the FDA's Accelerated Approval Program or Tricida's progress along this regulatory pathway. Other than the final challenged statements—Tricida's May 7, 2020 discussion of its May 1, 2020 late-cycle meeting with the FDA—Plaintiff does not challenge any of Tricida's descriptions of its interactions with the FDA.

The great majority of challenged statements are Tricida's undisputedly accurate references to the location of its Phase 3 clinical trial sites in the U.S. and Europe. Plaintiff claims that these statements were misleading insofar as Tricida failed to specify that the sites were in Eastern rather than Western Europe. Claims Chart Nos. A1-11; B1-10. We address this challenge first, and then turn to Plaintiff's attack on (1) Tricida's references to the Accelerated Approval Program during its June 12, 2019 investor presentation, (2) Tricida's references to the number of patients it expected would be randomized in the VALOR-CKD trial, and (3) Tricida's discussion on May 7, 2020 of its late-cycle meeting with the FDA. In no instance has Plaintiff pled facts showing that the challenged statements were false or misleading, let alone that Tricida intended to deceive investors.

III. DISCUSSION

Under the PSLRA, Section 10(b) plaintiffs must "state with particularity both the facts constituting the alleged violation and the facts evidencing scienter." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 876-77 (9th Cir. 2012) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007)). To adequately allege falsity, plaintiffs must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1)(B). To plead scienter, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). A court should deny a motion to dismiss "only if a reasonable person would deem the

inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. Plaintiffs must thus "plead with particularity facts that give rise to a 'strong'—i.e., a powerful or cogent—inference." *Id.* at 323.

A. Plaintiff Fails To Plead Facts Showing That Any Challenged Statement Was Materially False Or Misleading When Made

1. Plaintiff Fails To Plead Facts Showing That Tricida's References To Trials Conducted In "Europe" Were Materially False Or Misleading

The bulk of the complaint is devoted to Tricida's statements about the location of its Phase 3 trial sites. Tricida regularly informed and reminded investors that TRCA-301 was conducted "at 47 sites in the United States and Europe," and that TRCA-301E was conducted "at 29 sites in the United States and Europe." *E.g.*, ¶¶ 58, 63. Plaintiff does not contend that these statements—eleven in all—were false.[3] Plaintiff's theory is that the statements were misleading because Tricida purportedly did not disclose that a "majority of the trial sites for the TRCA-301/TRCA-301E trial were in Eastern Europe." *E.g.*, ¶ 56. According to Plaintiff, various features of the "Eastern European nephrology community" differ from those in Western Europe and the U.S., and the use of Eastern European trial sites therefore created a risk that the FDA would conclude that the results of TRCA-301 and TRCA-301E did not apply to U.S. patients. *Id.*; ¶¶ 10, 11, 23, 44, 55, Claims Chart Nos. A1-A11. Plaintiff accuses Tricida of concealing this risk by using the term "Europe."

This theory of fraud is dead on arrival. Facts of which this Court may take notice conclusively establish that Tricida did not conceal but explicitly *disclosed* the location of each of the Phase 3 trial sites. Tricida disclosed those locations in scientific journals, and amplified its disclosures on publicly available government websites. That is fatal to Plaintiff's claim. *E.g.*, *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 607 (9th Cir. 2014) (affirming dismissal where defendant disclosed purportedly concealed information in its public statements); *In re KeySpan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 377 (E.D.N.Y. 2003) ("dismissal is appropriate

[3] The first of the challenged geography-related statements appears in Tricida's June 5, 2018 press release. ¶¶ 54-57; Claims Chart No. A1. This statement is inactionable because it predates Plaintiff's putative class period, which begins on June 28, 2018. ¶ 3. "Plaintiff cannot rely on pre-Class Period statements to show falsity." *City of Roseville Emps.' Ret. Sys. v. Sterling Fin. Corp.*, 963 F. Supp. 2d 1092, 1111 (E.D. Wash. 2013), *aff'd*, 691 F. App'x 393 (9th Cir. 2017). The same is true of Statement C1 on the Claims Chart, which also appears in the June 5, 2018 release.

where the complaint is premised on the nondisclosure of information that was actually disclosed").

More specifically, on March 8, 2019, the medical journal *The Lancet* published the results of TRCA-301. The authors of that paper—who included Tricida executives—stated "[w]e did a multicentre, parallel, randomised, double-blind, placebo-controlled study at 37 sites (hospitals and specialty clinics) in eight countries (Bulgaria, Croatia, Georgia, Hungary, Serbia, Slovenia, Ukraine and the USA)." Ex. 18 at 1417, 1419. Seven of the eight countries listed—all but the U.S.—are in Eastern Europe. The appendix to the *Lancet* paper also listed each study location, showing that of the 37 sites, 25 were in Eastern Europe (with the remaining 12 in the U.S.). *Id.* at Appendix, page 1.

Three months later, on June 24, 2019, *The Lancet* published the results of TRCA-301E. Here again, the authors—including Tricida executives—disclosed the location of the trial sites: "We did a multicentre, randomised, blinded, placebo-controlled, 40-week extension of our 12-week parent study at 29 sites (hospitals and specialty clinics) in seven countries (Bulgaria, Georgia, Hungary, Serbia, Slovenia, Ukraine, and the USA)." Ex. 19 at 396-97. Six of the seven countries listed are in Eastern Europe. Like the March 2019 *Lancet* paper, the June 2019 paper included an appendix, this one listing 22 sites in Eastern Europe (with the remaining seven in the U.S.). *Id*. at Appendix, page 2. As Plaintiff acknowledges, Tricida repeatedly referred investors to the *Lancet* publications, both in SEC filings and at investor conferences. *E.g.*, ¶ 68 (". . . and in March 2019, the results of this trial were published in The Lancet"); ¶ 78 ("the pivotal portion of that trial actually just got published in the Lancet in March"); *see also* Ex. 5 at 4 ("The Lancet published the results of the TRCA-301 trial in March 2019 and the results of the TRCA-301E trial in June 2019").[4]

The two *Lancet* papers were not the sole sources of this geographical information, nor were they the earliest sources. As the sponsor of TRCA-301 and TRCA-301E, Tricida posted in-depth information about the trials on the website clinicaltrials.gov. On December 18, 2017, Tricida listed

[4] Tricida plainly had no obligation to repeat every detail in the *Lancet* articles in its SEC filings. *E.g.*, *Alexander v. Citigroup Glob. Mkts, Inc.*, 2013 WL 12077818, at *5 (C.D. Cal. Apr. 10, 2013) ("Securities laws do not require disclosure of information that is readily available in the public domain") (internal citations and quotation marks omitted); *In re Bank of Am. AIG Disclosure Sec. Litig.*, 980 F. Supp. 2d 564, 577 (S.D.N.Y. 2013) (dismissing complaint where news articles provided investors with "ready access to the very information that the plaintiffs assert should have been disclosed and the defendants are not liable for failing to reiterate that information"), *aff'd,* 566 F. App'x 93 (2d Cir. 2014).

on this website each of the original 47 locations for the TRCA-301 trial (of which 37 ultimately enrolled patients). Ex. 21. This list showed that 34 of the 47 sites were in Eastern Europe: one site in Bulgaria, two in Croatia, seven in Georgia, nine in Hungary, four in Serbia, four in Slovenia, seven in Ukraine, and thirteen in the U.S. *Id.* As the trial progressed, Tricida provided updates, dropping the trial sites that did not enroll patients. Ex. 22. On May 15, 2018, the website showed that 31 of the 44 then-participating sites—more than 70%—were in Eastern Europe. *Id.*

Tricida posted the same information for TRCA-301E. On March 29, 2018, Tricida listed 14 of 20 sites in Eastern Europe. Ex. 23. On May 4, 2018, Tricida provided an update showing that 22 of the 29 ultimate sites—more than 75%—were in Eastern Europe. Ex. 24 (one in Bulgaria, seven in Georgia, four in Hungary, one in Serbia, two in Slovenia, and seven each in Ukraine and the U.S.).

Given this public record, Plaintiff's contention that Tricida concealed the location of trial sites borders on the frivolous. The same is true of the fraud claim Plaintiff seeks to erect on this obviously defective foundation. After falsely accusing Tricida of hiding the location of the trial sites, Plaintiff seeks to demonstrate the materiality of the purported omission by piling up references to FDA and industry publications discussing possible differences between the East European and West European "nephrology communities," along with the attendant risks for FDA approval. ¶¶ 11, 56. These public materials make Defendants' point, not Plaintiff's. The fact that a majority of the trial sites were in Eastern Europe was publicly known—and so were the risks this entailed.

Plaintiff's claim would fail, moreover, even in the absence of these multiple geographical disclosures. Plaintiff does not contend that any statement Tricida made about the location of trial sites was false. Plaintiff's claim is that the statements were misleading by omission because Tricida used the word "Europe" in SEC filings without specifying "Eastern." But the reference to "Europe" is at most incomplete, and this is fatal. "[S]ection 10(b) and Rule 10b-5 prohibit only misleading and untrue statements, not statements that are incomplete"— including statements in which allegedly material information about clinical trials is omitted. *Rigel*, 697 F.3d at 880 n.8. The Ninth Circuit and district courts within it (including this Court) have thus repeatedly rejected omission claims that rest on the premise that public companies should have provided more complete information. *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1061 (9th Cir. 2014) ("We have

expressly declined to require a rule of completeness for securities disclosures"); *Colyer v. AcelRx Pharms., Inc.*, 2015 WL 7566809, at *5-6 (N.D. Cal. Nov. 25, 2015) (accurate descriptions of Phase 3 trial are not misleading by way of omission; dismissing complaint); *Costabile v. Natus Med. Inc.*, 293 F. Supp. 3d 994, 1012 (N.D. Cal. 2018) ("The simple fact that the [disclosure] could have included more detail . . . without more, does not render the statement misleading"). Plaintiff's claim that Tricida omitted the word "Eastern" clearly fails on both factual and legal grounds.

2. Plaintiff Fails To Plead Facts Showing That Tricida's Risk Disclosures About Foreign Trial Sites Were Materially False Or Misleading

In addition to its multiple geographical disclosures in medical publications and on government websites, Tricida repeatedly cautioned investors in SEC filings that the majority of the patients enrolled in the Phase 3 trials were treated outside the U.S., and that there was a risk that the FDA would not accept clinical data from overseas. Tricida warned investors that "[w]e conducted the TRCA-301 trial and are conducting the TRCA-301E trial with majority enrollment outside the United States and may, in the future, conduct clinical trials of our product candidates outside the United States. *The FDA may not accept such foreign clinical data . . . .*" ¶ 60 (emphasis altered). Tricida further cautioned that while "[t]he foreign clinical data should also be applicable to the U.S. population and U.S. medical practice," the FDA's decision whether to accept the data would turn on a variety of factors, "includ[ing] differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country." *Id.*

Plaintiff challenges these disclosures, singling out the very statements in which Tricida warned of the risks associated with clinical trials with "majority enrollment outside the United States." Claims Chart Nos. B1-B10. Plaintiff contends that these statements show that Tricida knew, but omitted to disclose, that the Phase 3 trials were conducted not just outside the U.S. but specifically in Eastern Europe. ¶ 60. This is obviously wrong. Tricida did not conceal the fact that the majority of sites and patients were in Eastern Europe; it consistently disclosed that information.

3. Plaintiff Fails To Plead Facts Showing That Tricida's References To "Multicenter" Phase 3 Trials Were Materially False or Misleading

Plaintiff next challenges Tricida's statement that it had "recently completed a randomized,

double-blind, placebo-controlled, multicenter pivotal Phase 3 clinical trial for [veverimer], known as TRCA-301." *E.g.* ¶ 58; Claims Chart Nos. C1-C11. Plaintiff focuses on "multicenter," contending that because the FDA's February 2021 Appeal Denied Letter "noted concerns around the trial results being strongly influenced by a single site," the term "multicenter" was misleading. ¶¶ 9, 59.

Plaintiff again fails to state an omission claim. Tricida's statements that the Phase 3 trials were "multicenter" are demonstrably true: Plaintiff does not dispute that 37 sites enrolled patients in TRCA-301 and 29 sites enrolled patients in TRCA-301E. Nor can Plaintiff seriously dispute that Tricida publicly disclosed the location of each site. Defendants did not have a duty to go further and disclose the precise enrollment figures for each site. "[I]t bears emphasis that § 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Any time a public company speaks, "there are likely to be additional details that could have been disclosed but were not." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). As noted, the Ninth Circuit applied this rule to the context of clinical trials in *Rigel*, holding that "as long as the omissions do not make the actual statements misleading," a company is not required to disclose every relevant fact about a trial, "even if investors would consider the omitted information significant." 697 F.3d at 880 n.8. Again, public companies do not owe investors any "duty of completeness." *Supra* at 11.

Notably, Tricida did not say or suggest that the sites enrolled patients on a proportional basis, or were equally responsible for favorable results. Consequently, nothing in Tricida's use of the term "multicenter"—which Plaintiff does not claim was inaccurate—"affirmatively creat[ed] an impression of a state of affairs that differ[ed] in a material way from the one that actually exist[ed]." *Brody*, 280 F.3d at 1006; *see also, e.g.*, *Philco Inv., Ltd. v. Martin*, 2011 WL 500694, at *8 (N.D. Cal. Feb. 9, 2011) (dismissing complaint where challenged statement about clinical trial "did not contain all of the detail Plaintiffs would have liked," but was nevertheless "not misleading").

Plaintiff's contention that the FDA *ultimately* cited a concern with the influence of one site in denying Tricida's appeal does not make the term "multicenter" misleading either. Section 10(b) plaintiffs do not allege fraud by reading later FDA determinations backwards onto a company's statements about its clinical trials or NDA. Judge Seeborg recently amplified this point in *Zogenix*, a

case in which the FDA noted that the company had not discussed certain toxicity studies in its NDA, and accordingly issued a refuse-to-file letter. *Immanuel Lake v. Zogenix*, 2020 WL 3820424 (N.D. Cal. Jan. 27, 2020). The court rejected the plaintiffs' claim that the company had deceived investors by failing to disclose this aspect of its NDA: That claim was based on "the very sort of fraud-by-hindsight reasoning that the PSLRA was enacted to avoid." *Id.* at *8. The court then elaborated:

> [W]ere plaintiffs' version of falsity the law, a pharmaceutical company could be sued for securities fraud each and every time it received a NDA rejection from the FDA. Potential plaintiffs could merely parrot any deficiency identified by the FDA . . . and then claim the company concealed from the market that it failed to include this "necessary" piece of information in its application.

Id. at * 9. That reasoning applies equally to Plaintiff's claims here. Later regulatory determinations do not show that Tricida's statements about its clinical trials were false when made.

4. Plaintiff Fails To Plead Facts Showing That Tricida's June 12, 2019 References To The Accelerated Approval Program Were Materially False Or Misleading

Plaintiff next challenges references Klaerner made to the Accelerated Approval Program during a June 12, 2019 investor presentation. Claims Chart Nos. E1-E2. Plaintiff's attack depends entirely on his own characterization of those references—not on the words Klaerner actually used.

As noted, Tricida discussed the Accelerated Approval Program repeatedly during the purported class period, explaining to investors that a drug sponsor (1) may submit an NDA based on a trial with an unvalidated surrogate endpoint, but (2) will also be required to perform a post-approval trial demonstrating a favorable clinical outcome. *Supra* at 4-5. Plaintiff does not challenge any of those statements. Nor does Plaintiff challenge Tricida's reports of favorable Phase 3 results, including results from TRCA-301E, the safety extension trial. Tricida reported that TRCA-301E not only met its primary safety endpoint and secondary efficacy endpoints related to the blood bicarbonate surrogate marker, but also provided early evidence of *clinical* benefit. *Supra* at 4.

> At the June 12, 2019 investor presentation, Klaerner described the situation as follows: [In the Phase 3 trial], all you expect to do is to show a surrogate effect, and then you have a post-market commitment that ultimately then, you confirm that, that surrogate is going to translate. Now we found ourselves with 1-year safety extension data that showed clinical benefit. And I think that excitement . . . I think that is a good thing to have.

¶ 78. Plaintiff, again, does not dispute that TRCA-301E showed a clinical benefit. Plaintiff's claim instead is that with this statement, Klaerner "materially misrepresented that approval through the

[Accelerated Approval Program] is somehow *simpler and easier* than approval along the standard path." ¶ 80 (emphasis added). Plaintiff contends that Accelerated Approval is not simple or easy because the sponsor must ultimately show a clinical benefit through a post-marketing trial. *Id.*

As a fraud claim, this is difficult to fathom. Klaerner did not say that Accelerated Approval would be "simpler or easier" than anything. Nor did he omit the fact that Tricida would need to perform a post-marketing study showing clinical benefit. Indeed, he made precisely the latter point in the very statement Plaintiff challenges ("and then you have a post-marketing commitment").

But even if "simpler and easier" had been Klaerner's term rather than Plaintiff's, no reasonable investor could have been misled by it. Information about Accelerated Approval was available not only through Tricida's many unchallenged descriptions but also from the FDA. Plaintiff himself emphasizes the FDA's guidance, citing an article on the FDA's website for the proposition that "[d]rug candidates evaluated via the [Accelerated Approval Program] must still meet the same statutory standards for safety and efficacy: substantial evidence based on adequate and well-controlled clinically [sic] investigations." ¶ 80. The FDA materials underscore that investors were fully apprised of the risks inherent in Accelerated Approval, and could discern for themselves whether it was "simpler and easier" than other options. This dooms Plaintiff's claim. Courts reject allegations of fraud where purportedly concealed approval risks are publicly known. *E.g.*, *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015) (dismissing claim that company concealed the risk that the FDA would deny approval because trials were single-blinded; the FDA's preference for double-blinding was publicly known), *aff'd*, 816 F.3d 199 (2d Cir. 2016).

Plaintiff also challenges Klaerner's statement, from the same June 12, 2019 presentation, that "We have the ability to submit our NDA with just one pivotal trial that shows a surrogate effect, and we've completed that." ¶ 78. Plaintiff does not dispute the truth of this statement; his claim is that "Klaerner misleadingly presented the single phase 3 efficacy trial as a strength" and an "accomplishment." ¶ 83. This is sheer invention. Klaerner did not use the words "strength" or "accomplishment." He accurately stated that under the Accelerated Approval Program, a sponsor may submit an NDA based on a surrogate endpoint trial—and that Tricida had done just that. Plaintiff pleads no facts showing that this was misleading.

5. Plaintiff Fails to Plead Facts Showing That Statements Regarding The Design Of VALOR-CKD Were Materially False Or Misleading

Plaintiff next attacks Tricida's statements about the VALOR-CKD trial, and in particular the statement that Tricida had designed the trial with a target of 1600 randomized patients. Claims Chart Nos. D1-D6. In the randomization process enrolled patients are assigned to a particular treatment arm—in the case of VALOR-CKD, to veverimer or placebo.

In the statements Plaintiff challenges, Tricida discussed the 1600-patient figure in the context of VALOR-CKD's "power." "Power," in connection with clinical trials, is a statistical concept that reflects the probability that a test will yield a statistically significant result if the research hypothesis is true. Tricida described its power calculation as follows:

> Based on the magnitude of the increase in blood bicarbonate observed in our pivotal Phase 3 trial, TRCA-301, and the inverse relationship between blood bicarbonate and the risk of renal events described by the Predictive MA Model, we have determined that randomizing 1600 subjects to [veverimer] or placebo in a 1:1 ratio will result in 90% power to show a 30% to 35% reduction in renal events in the VALOR-CKD study.

¶ 71. Tricida and the FDA referred to the predictive model used to calculate the power of VALOR-CKD as the "Tangri model," in reference to Dr. Navdeep Tangri, a nephrologist and professor of medicine at the University of Manitoba who worked with Tricida to develop the model. ¶ 28.

Plaintiff claims that Tricida's statements about the 1600-patient figure were false in light of Tricida's disclosure on February 25, 2021 that the FDA ultimately concluded that VALOR-CKD was "underpowered to detect the effect size . . . predicted by the Tangri model . . . ." ¶ 9. Plaintiff again simply reads the FDA's later determination backwards onto the challenged statements, with no supporting facts and nothing explaining—as required by law—"why the difference between the earlier and the later statements is not merely the difference between two permissible judgments, but rather the result of a falsehood." *In re Glenfed, Inc. Sec. Litig.*, 42 F.3d 1541, 1549 (9th Cir. 1994) (en banc). Plaintiff's theory of fraud fails for this and multiple related reasons.

First, in a familiar pattern, Plaintiff substitutes his own words for Tricida's. Plaintiff claims that Tricida stated that it had "determined 1,600 subjects to be the necessary number." ¶ 72. But Tricida did not say that 1600 or any other number of randomized patients was "necessary." Tricida said that 1600 randomized patients, along with other numerical inputs, generated a particular power

for the study. ¶ 71. The contention that any single number of randomized patients was necessary or correct is Plaintiff's, not Tricida's, and it is not supported by any fact Plaintiff alleges.

Plaintiff next contends that Tricida "had set a target internally of enrolling 4,000 patients." ¶ 72-73. Plaintiff attributes this allegation to CW1, one of the two purported confidential witnesses in this case. *Id.* But neither Plaintiff nor CW1 explains how this putative *enrollment* target relates to the 1600 patients Tricida consistently said it expected to be *randomized* in VALOR-CKD. More significantly, Plaintiff does not explain how CW1, who is alleged to have worked as a "Clinical Trial Assistant" for eight months, came to learn of the number of patients Tricida sought to have either enrolled or randomized in VALOR-CKD. Neither Plaintiff nor CW1 provides information about the origin of this number, how or by whom it was calculated, by whom it was used, or for what purpose. CW1 baldly states that 4000 was the enrollment target—and no more. Under controlling law, this is insufficient. Where Section 10(b) plaintiffs rely solely on confidential witness allegations to establish falsity or scienter, they must provide a "basis for determining that the witnesses in question have personal knowledge of the events they report." *Zucco Partners v. Digimarc Corp.*, 552 F.3d 981, 995 (9th Cir. 2009). Plaintiff has not provided the required basis here.

CW1's reference to a 4000-patient enrollment goal is nonsensical in any event, and so is the theory of fraud Plaintiff seeks to build on it. Tricida told investors in its June 2018 IPO filings that it expected 1400-1600 patients to be randomized in VALOR-CKD. Ex. 1 at 4. At that point, no patient had yet been enrolled: VALOR-CKD did not begin until the fourth quarter of 2018. ¶ 29. Plaintiff contends that two things occurred during the early months of the trial. First, "[r]egardless of what Tricida had previously anticipated the necessary VALOR-CKD patient enrollment to be, by March 2019, Tricida had set a target internally of enrolling 4,000 patients." ¶ 72. And second, Tricida "struggled to recruit patients." ¶ 29. As part of that struggle, CW1 says, Klaerner became angry with the clinical research organization Tricida had retained to handle recruitment (although CW1 does not seek to link this to any particular enrollment or randomization figure). ¶ 73. After that, Plaintiff says, Tricida reverted to a 1600-patient figure to avoid delaying submission of its NDA. ¶ 72. Plaintiff's narrative thus appears to be that (1) Tricida initially anticipated that 1600 patients would be randomized, and disclosed this in June 2018, (2) by March 2019, Tricida had

switched to an internal target of 4000 enrolled patients, at the same time as it struggled with enrollment, and (3) Tricida then switched back to a 1600-patient randomization target. Plaintiff pleads no facts to support this story of multiple undisclosed switches back and forth between targets, and it is plainly implausible.

Plaintiff's contention that the FDA ultimately told Tricida that it believed VALOR-CKD was underpowered, ¶ 72, does not demonstrate falsity either. Plaintiff does not allege that the FDA communicated any such determination to Tricida at the time of the challenged statements, and that itself is fatal. *E.g.*, *In re Dynavax Sec. Litig.*, 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018) (rejecting allegation that "because the FDA later issued a CRL halting the approval process, [the company] must have known earlier that approval was in jeopardy"; the complaint contained no allegation "that the FDA had indicated that the [safety data at issue] would halt the approval timeline at some point before it issued its . . . CRL").

The law is equally clear that plaintiffs cannot state a Section 10(b) claim by second-guessing a drug developer's scientific or statistical judgments. *Rigel*, 697 F.3d at 877 (affirming dismissal where "Plaintiff is alleging that Defendants should have used different statistical methodologies, not that Defendants misrepresented the results they obtained from the methodologies they employed"); *Mulquin v. Nektar Therapeutics*, 2020 WL 7773580, at *10 (N.D. Cal. Dec. 30, 2020) ("merely alleging that defendants should have used different statistical methodology in their drug trial is not sufficient to allege falsity") (quoting *Rigel*). Courts therefore routinely reject fraud claims premised on challenges to trial design. *Rigel*, 697 F.3d at 877 (affirming district court's holding that "disagreements over statistical methodology and study design are insufficient to allege a materially false statement"); *Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013). That is precisely the claim Plaintiff seeks to advance here. Plaintiff contends that VALOR was not adequately powered and "needed 4,000 subjects." ¶¶ 73, 123. Such disputes over design and method are not justiciable.

Plaintiff's attack on the VALOR-CKD trial design finally fails because it is based on a misunderstanding of the underlying statistics. On February 25, 2021, Tricida reported that in denying its intra-agency appeal, the FDA had stated that VALOR was "underpowered to detect the effect size predicted (13%) by the original Tangri model . . . based upon the placebo-subtracted

mean treatment effect observed in the [Phase 3] trial." ¶ 72. From this statement, Plaintiff leaps to the conclusion that VALOR was "under-enrolled." ¶ 119. But Plaintiff fails to plausibly allege why a trial that is "underpowered" is also necessarily "under-enrolled." Multiple factors are relevant to the powering calculation; the number of randomized subjects is only one. ¶¶ 71, 97 (other inputs for powering VALOR-CKD include the magnitude of the surrogate effect and the relationship between surrogate and clinical effects). Plaintiff acknowledges that Tricida amended VALOR's trial protocol in late 2020. ¶¶ 118-19. That amendment changed the power of the study but did not increase the number of randomized patients above the original 1600. *Id.*; Ex. 17 at 2.[5] This further exposes the fallacy of Plaintiff's misleadingly simplistic equation between power and enrollment. Plaintiff's attack on Tricida's references to the 1600-patient randomization target thus fails at every level. It is grounded in hindsight, based on incoherent confidential witness allegations, premised on a legally improper attack on trial design, and dependent on a misunderstanding of the underlying statistics.

6. Plaintiff Fails To Plead Facts Showing That Tricida's May 7, 2020 Discussion Of The May 1, 2020 Late-Cycle Meeting Were Materially False Or Misleading

Plaintiff claims that Tricida made two final false or misleading statements during its May 7, 2020 earnings call. Claims Chart No. E3. In both statements, Klaerner discussed Tricida's May 1, 2020 late-cycle meeting with the FDA. Klaerner stated, first, that the FDA had "indicated that it currently does not plan to hold an AdCom to discuss veverimer due in part to the logistical challenges posed by COVID-19." ¶ 101. Plaintiff contends that this statement was false, alleging that the FDA's plan to proceed without an Advisory Committee meeting "was not, primarily, due to the logistical challenges posed by COVID-19, but instead due to the FDA's concerns that there were too many problems with the NDA." ¶ 102. This claim is easily disposed of. Plaintiff cites no facts showing that the FDA did *not* tell Tricida that it had canceled the meeting in part because of

[5] In the protocol amendment, Tricida, again working with Dr. Tangri, developed a new "Time-Dependent Predictive Model" to model the connection between the change in the surrogate marker and the risk of CKD progression. Tricida explained in the amendment that the magnitude of the change from baseline in the surrogate marker observed in the Phase 3 trials was "best described using the between-group difference in the medians, rather than the difference in the LS means, as the data are not normally distributed." Ex. 17 at 2. With the amendment, VALOR-CKD had "87% power to show a 24% difference in primary endpoint events," with the same 1600-patient sample size. *Id.* (In denying Tricida's appeal, the FDA did not consider this protocol amendment. *Id.*)

COVID. The public record, meanwhile, shows that the FDA canceled or postponed many Advisory Committee meetings in the early months of the pandemic. Ex. 20 at 8-9.

Plaintiff further attacks Klaerner's statement that, during the May 1, 2020 meeting, Tricida "took the opportunity to address outstanding review issues," including "the magnitude and durability of the treatment effect on the surrogate [marker]" in the Phase 3 trials and the benefit of veverimer for U.S. patients. ¶ 101. Plaintiff claims that Klaerner misleadingly omitted facts Tricida later revealed on August 6, 2020, when it reported that during the May 1, 2020 meeting, it had addressed "two substantive review issues that the FDA had raised in advance of the meeting, namely concerns related to the magnitude and durability of the treatment effect on the surrogate marker . . . and the applicability of data from the TRCA-301 and TRCA-301E trials to the U.S. population." ¶ 102.

Plaintiff's claim fails because here too, Tricida disclosed the purportedly concealed facts. Tricida's disclosure on August 6, 2020—which Plaintiff claims revealed the "truth" about the late-cycle meeting purportedly concealed on May 7, 2020—in reality *matches* the challenged May 7, 2020 statement. On both May 7, 2020 and August 6, 2020, Tricida noted that it had addressed the FDA's "review issues" during the late-cycle meeting. Tricida used identical language in identifying the first of the two issues, stating both on May 7, 2020 and August 6, 2020 that the issue was "the magnitude and durability of the treatment effect on the surrogate" marker. ¶¶ 101-102. Tricida also used similar language in identifying the second issue, stating on May 7 that it had addressed "the clinical benefit that the U.S. patients get," and on August 6 that it had addressed "the applicability of data from the [Phase 3 trials] to the U.S. population." *Id.*; Ex. 7 at 21; Ex. 15 at 10. Plaintiff's attempt to show that Tricida's May 7, 2020 statement was false by reference to Tricida's August 6, 2020 disclosure in reality shows the opposite: Tricida disclosed the same information on both dates.

This is not to say that Tricida held the same belief about the FDA's likely course of action on May 7, 2020 and on August 6, 2020. Between those two dates, the ground shifted dramatically: The FDA issued its deficiency notice on July 14, 2020. For that reason, Tricida was able to tell investors on August 6, 2020 what it could not have told them on May 7, 2020: that it expected not approval but a CRL denying approval. ¶ 102. But that does not show that Tricida's May 7, 2020 statements about the late-cycle meeting were false or misleading when made.

To the extent Tricida conveyed more information about the May 1, 2020 late-cycle meeting after it had received the July 14, 2020 deficiency notice than it conveyed before that date, this does not show falsity either. "The FDA approval process necessarily involves a dialogue between the company and the agency," and companies seeking FDA approval have "'no legal obligation to loop the public into each detail of every communication with the FDA.'" *Dynavax*, 2018 WL 2554472, at *7 (quoting *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017)); *see also, e.g.*, *Sanofi*, 87 F. Supp. 3d at 541 ("in a series of cases, courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review") (collecting authorities); *In re Arrowhead Pharms., Inc. Sec. Litig.*, 2017 WL 5635422, at *5 (N.D. Cal. Sept. 20, 2017). Given the fluid nature of the approval process, "[r]easonable investors would expect that the company and the FDA would be engaged in a dialogue about the sufficiency of the clinical trials and that such dialogue inherently would include contrary views." *Dynavax*, 2018 WL 22554472, at *7. Under settled law, Tricida had no obligation, on May 7, 2020, to report all details of the May 1, 2020 late-cycle meeting. The omission of any such details accordingly does not render the statements Tricida did make about the meeting on May 7, 2020 actionable.

B. Plaintiff Fails To Plead Facts Creating The Required Cogent and Compelling Inference Of Intentional Fraud

Plaintiff's allegations are as defective on scienter as they are on falsity grounds. Plaintiff bears the burden of pleading particularized facts creating a strong inference that Defendants intentionally defrauded investors. 15 U.S.C. § 78u-4(b). The scienter analysis is "inherently comparative"; a court must "compare the malicious and innocent inferences cognizable from facts pled in the complaint and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference." *Zucco*, 552 F.3d at 991. Courts evaluate scienter allegations both individually and holistically. *Tellabs*, 551 U.S. at 326.

Knowledge of allegedly omitted information does not establish scienter. Where, as here, a Section 10(b) plaintiff targets statements about clinical trials and FDA approval under an omission theory, an allegation that the company or its executives knew the purportedly omitted information

does not in itself create a strong inference of scienter. Rather, the plaintiff must show that the defendant knowingly breached an established duty to disclose that information. *AcelRx*, 2015 WL 7566809, at *13 ("To be clear, knowing about the existence of [certain information bearing on approval] and knowing that one should report [that information] to the public are two different things"); *In re GeoPharma, Inc., Sec. Litig.*, 411 F. Supp. 2d 434, 446 (S.D.N.Y. 2006) ("a failure to disclose particular information, by itself, can only constitute recklessness if there was an obvious duty to disclose that information"). Plaintiff's contention that Tricida knew the location of its trial sites, or knew of the role played by one site, ¶ 123, does not support a strong inference of scienter. Neither shows that Defendants intentionally deceived investors by withholding information they knew they had a duty to disclose—which is what Plaintiff must plead.

Counterintuitive theories of motivation do not establish scienter. Plaintiff focuses largely on motivation in an effort to create an inference of scienter. ¶¶ 122-23. But under controlling law, such allegations are "not independently sufficient" to establish scienter. *Intuitive Surgical*, 759 F.3d at 1062. Moreover, the Ninth Circuit has recently emphasized, in the context of clinical trials and FDA approval, that courts assessing motivation must reject allegations that "do[] not resonate with common sense." *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 416 (9th Cir. 2020). Pursuant to that principle, courts reject economically counterintuitive scienter theories identical to the one Plaintiff advances here—that a drug sponsor would knowingly invest resources in a flawed attempt to secure FDA approval, rather than doing everything it could to eliminate flaws and improve the chances of approval. "The idea that [a] company, highly dependent on the success of [a] new drug, would knowingly or recklessly [carry] on a defective trial—so that any defects were not remedied—virtually defies reason." *Jun Shi v. Ampio Pharms., Inc.*, 2020 WL 5092910, at *5 (C.D. Cal. June 19, 2020) (internal quotation marks and citation omitted; dismissing complaint on scienter grounds). Where securities plaintiffs cannot refute the obvious "benign explanation" that a drug sponsor has "every incentive to get it right the first time, and to put [its drug] on the path to approval," courts decline to infer scienter. *Zogenix*, 2020 WL 3820424, at *11.

Plaintiff cannot refute that obvious benign explanation here. Plaintiff emphasizes the significance of veverimer to Tricida—it is the Company's only drug candidate, ¶ 124—but as in

other instances, this makes Defendants' point, not Plaintiff's. The higher the stakes, the greater Tricida's motivation to "get it right the first time." Plaintiff also seeks to introduce contrary motivations by listing Klaerner's stock sales between December 2018 and February 2021, ¶ 122, but every sale was made under a Rule 10b5-1 trading plan, and hence was not discretionary. Ex. 13. Such sales do not support an inference of scienter—although they may refute it. *Metzler Inv. GmbH v. Corinthian Coll., Inc.*, 540 F.3d 1049, 1067 n.11 (9th Cir. 2008).

Unable to escape the fact that Klaerner's sales were made under a trading plan, Plaintiff invites the Court to disregard it, alleging that "this 10b5-1 plan was itself first implemented amidst Klaerner and Tricida's ongoing securities fraud." ¶ 122. But that is an artifact of Plaintiff's own pleading tactics, not a sign of fraud. Plaintiff has chosen to allege a class period that begins with Tricida's June 2018 IPO. Because a trading plan is relevant only when stock is publicly traded, Klaerner literally could not have adopted such a plan before he was, in Plaintiff's self-serving terms, "amidst" the alleged fraud. That entirely undermines Plaintiff's suggestion the trading plan can be ignored. *See In re Taleo Corp. Sec. Litig.*, 2010 WL 597987, at *12 (N.D. Cal. Feb. 17, 2010) (in the context of a three year-long class period, "the fact that [defendants] may have entered into the [10b5-1 trading] plans during the Class Period is not inherently suspicious, given its length").

But even if the Court were to disregard Klaerner's trading plan, Plaintiff would bear the burden of demonstrating that Klaerner's stock sales were suspicious in timing or amount, which is generally shown by comparing class-period to pre-class-period sales. *E.g.*, *Ronconi v. Larkin*, 253 F.3d 423, 435 (9th Cir. 2002); *In re Silicon Storage Tech., Inc. Sec. Litig.*, 2006 WL 648683, at *18 (N.D. Cal. Mar. 10, 2006). Plaintiff has certainly not shown that the timing of Klaerner's sales was unusual; because of his own pleading tactics, Plaintiff has no pre-class-period sales with which to compare them. As to amount, the majority of the sales Plaintiff identifies were in the amount of 4000 shares; the largest by far was 57,822 shares. ¶ 122. These numbers can be understood only in the context of Klaerner's overall stock holdings, which during the class period ranged from 1.9 million to 2.1 million shares (rounded). Ex. 10 at 26; Ex. 11 at 31; Ex. 12 at 40. Even the largest of the sales was a very small fraction of Klaerner's holdings. Such sales are not suspicious in amount.

Plaintiff finally seeks to show improper motivation by noting that Tricida sold stock, both in

its June 2018 IPO and in an April 2019 secondary offering. ¶ 123. But "allegations of routine corporate objectives . . . are not, without more, sufficient to allege scienter; to hold otherwise would support a finding of scienter for any company that seeks to enhance its business prospects." *Rigel*, 697 F.3d at 884. This is no less true of stock offerings than of other corporate transactions. *Webb v. SolarCity Corp.*, 884 F.3d 844, 856 (9th Cir. 2018) ("Surely every company that goes public wants to maximize its apparent profitability prior to its IPO and to maintain a high share price afterward in order to finance acquisitions and expand"). If anything, the timing of Tricida's offerings weighs against scienter. When Tricida went public in June 2018, it had already successfully completed its pivotal Phase 3 trial. By the time of the secondary offering, as Plaintiff notes, Tricida was raising funds for commercialization. ¶ 123. To posit stock offerings as signs of malign motivation, as Plaintiff does, makes little sense when a company has largely self-funded the enormous expense of Phase 3 trials.

Plaintiff's "core operations" allegations do not establish scienter. Plaintiff next stresses the importance of veverimer to Tricida, claiming that the drug was the Company's "core operation[]," and alleging that Tricida's "entire future hung on the success of bringing veverimer to market." ¶ 124. As noted, courts have held that a company's dependence on a single drug weighs *against* an inference of fraud, as it increases the importance of "getting it right" in the approval process. *Supra* at 21-22. In any event, a plaintiff invoking the core operations principle must do more than merely allege that a particular product or area of business is centrally important to a company. *E.g.*, *Iron Workers Local 580 Joint Funds v. Nvidia Corp.*, 2020 WL 1244936, at *12 (N.D. Cal. Mar. 16, 2020) ("Simply alleging that gaming is [the company's] core business does not give rise to an inference of scienter"). If the law were otherwise, courts would always be required to infer scienter as to some aspect of a company's business. This Court has accordingly held that to create an inference of scienter, even as to core operations, a plaintiff must show that defendants made a false or misleading statement, that its false or misleading nature was obvious, and, in the case of an omission, that defendants knew they had an obligation to report information to the public. *AcelRx*, 2015 WL 7566809, at *13. Plaintiff alleges no fact supporting any of those necessary steps here.

Plaintiff's CW allegations do not establish scienter. Plaintiff's final scienter allegations,

related to their two confidential witnesses, are glaringly defective. According to CW2, a purported sales executive, Klaerner referred to meetings that Tricida was waiting for the FDA to schedule, and planned a veverimer launch party at the Ritz-Carlton at Half Moon Bay. ¶ 125. But references to FDA meetings cannot possibly show an intent to deceive investors, and plans for a launch party show confidence in approval. CW1, discussed above, purportedly said that Klaerner attended meetings related to an FDA inspection, as well as meetings related to VALOR-CKD enrollment. *Id.* But CW1 says nothing about the content of the meetings related to inspection; as to enrollment, CW1 says only that Klaerner became angry when enrollment was slow. *Supra* at 17. CW1 makes a conclusory reference to a 4000-patient enrollment target, but does not say that *Klaerner* knew about or endorsed this target. None of this supports an inference of deliberate fraud.

Plaintiff's scienter allegations fail when considered holistically. Plaintiff's scienter allegations are no stronger when viewed collectively. Most obviously, Plaintiff has not dispelled the benign inference that Tricida strove earnestly to secure approval for veverimer, carefully choosing a regulatory pathway that appeared to match the drug and disease it targeted, and forthrightly communicating its plans and the attendant risks to investors. Indeed, Plaintiff concedes that Tricida repeatedly warned investors of the risk posed by its use of foreign trial sites. Tricida's thorough disclosure of this and other risks, *supra* at 5-6, further undermines any inference of scienter. *E.g.*, *Kader v. Sarepta Therapeutics, Inc.*, 887 F. 3d 48, 58 (1st Cir. 2018) ("providing warning to investors, or otherwise disclosing potential risks, erodes inferences of scienter"); *Jasin v. Vivus, Inc.*, 2016 WL 1570164, at *22 (N.D. Cal. Apr. 19, 2016) ("the thoroughness of [the] risk disclosures . . . negate[s] any inference of scienter even further").

Finally, Tricida's conduct throughout the purported class period is wholly inconsistent with fraud. Tricida poured resources into clinical trials, completing its pivotal Phase 3 trial before its IPO. In the 18 months before approval was expected, Tricida invested heavily in commercialization. Tricida reported early in 2019 that it had hired a highly experienced Commercial Officer. Ex. 16. Later in 2019, Tricida reported hiring additional executives, as it "transform[ed] [itself] into a commercial organization that is preparing to launch veverimer, if approved." Ex. 4 at 5. In August 2020, Tricida reported that it had hired 40 specialty account managers in key territories, in addition

to the leadership team and regional business directors hired to manage commercialization. Ex. 7 at 22. Each of these acts demonstrates Tricida's commitment to the anticipated commercial launch.

When the FDA shifted course beginning in July 2020, Tricida was compelled to reverse those efforts. As Tricida reported, it let 43 employees go after receiving the FDA's August 2020 CRL, incurring restructuring costs of $2.5 million. Ex. 8 at 21-22. Even at that time, Tricida retained part of its sales force, hoping for progress with the FDA at the October 2020 End-of-Cycle meeting. After that meeting, Tricida severed an additional 50 employees, with aggregate restructuring costs of $13.2 million. *Id.* at 22. Hiring a commercial organization is an enormous expense, and Plaintiff's suggestion that Tricida both incurred that expense and exposed itself to an additional $13.2 million in restructuring liability—all while believing that FDA approval was dubious—is impermissibly counterintuitive. *See Endologix*, 962 F.3d at 416 (rejecting theory of scienter that "does not make a whole lot of sense"). Meanwhile, as Tricida has told the market, its investment in veverimer continues to this day, as do its plans for eventual approval: VALOR-CKD is ongoing, and Tricida is funding it. Ex. 9 at 17-18. All of this squarely contradicts Plaintiff's narrative of fraud—which in any event is refuted again and again by Tricida's disclosure of the information Plaintiff alleges was concealed.

IV. CONCLUSION

For all of these reasons, the Court should dismiss Plaintiff's Section 10(b) claim. The Court should also dismiss Plaintiff's claim against Klaerner for control person liability under Section 20(a) of the Exchange Act, which depends on a primary violation of Section 10(b). *E.g., City of Dearborn Heights v. Align Tech., Inc.*, 856 F.3d 605, 623 (9th Cir. 2017).

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Respectfully submitted,

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